UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,040	07/19/2004	Hans H. Liao	6682-63358-09	7115

7590 04/16/2007

Scott Pribnow
Cargill Incorporated
Law Department
15407 McGinty Road West
Wayzata, MN 55391-5624

EXAMINER	
SLOBODYANSKY, ELIZABETH	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	10/502,040	LIAO ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky, PhD	1652.	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Elizabeth Slobodyansky, PhD*. (3)_____.

(2) *Sheree Lynn Rybak, PhD (attorney)*. (4)_____.

Date of Interview: *10 April 2007*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *draft claims (attached)*.

Identification of prior art discussed: *US 6,248,874 (Frey et al); US 20030113882-A1 (Frey et al)* .

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

E. Slobodyansky

Examiner's signature, if required

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: With regard to the112, 1st written description rejection, it was clarified that describing a novel enzyme just by function as in claim 47, for example, is insufficient and reference to the sequence or the combination of the properties is necessary. With regard to the 102 rejections over Frey references, Dr. Rybak indicated that 5 mismatches between the amino acid sequence of SEQ ID NO:30 herein and SEQ ID NO:2 in Frey are shown at Fig. 5 of the specification as mismatches between the sequences of alanine- and lysine aminomutases. Dr. Rybak indicated that alanine aminomutase activity shown in Example 5 of US 20030113882 is measured under artificial conditions and is not reproducible in vivo. Dr. Rybak intends to provide evidence of that.

KLARQUIST SPARKMAN, LLP

INTELLECTUAL PROPERTY LEGAL SERVICES • INCLUDING PATENTS, TRADEMARKS, COPYRIGHTS & LITIGATION • SINCE 1941

One World Trade Center • 121 S.W. Salmon Street • Suite 1600 • Portland, Oregon 97204 • U.S.A.

Telephone: 503-595-5300 • www.klarquist.com

Facsimile: 503-595-5301

FAX TRANSMITTAL

DATE:	April 10, 2007
TO:	Elizabeth Slobodyansky Art Unit 1652
FAX PHONE NO.:	571-273-0941
FROM:	Sheree Lynn Rybak, Ph.D.
RE:	U.S. Application No. 10/502,040
OUR FILE:	6682-63358-09
NO. OF PAGES	9 (including this cover page)
CONTACT INFO:	If you do not receive all pages or if you have problems receiving transmittal, please call us at (503) 595-5300 as soon as possible and ask for Deborah Martin.

MESSAGE: Please see attached draft.

RJP:SLR 04/10/07 680205.doc CGL01/0125US1:A00066-00517.0010
PATENT

Attorney Reference Number 6682-63358-09
Application Number 10/502,040

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Liao et al.
Application No. 10/502,040
Filed: July 19, 2004
Confirmation No. 7115
For: ALANINE 2, 3-AMINOMUTASE
Examiner: Elizabeth Slobodyansky
Art Unit: 1652
Attorney Reference No. 6682-63358-09

TO: 1-571-273-0941

DRAFT: DO NOT ENTER

Dear Examiner Slobodyansky:

Attached is a draft amendment and response for your review, for our 4 pm EST telephone interview today.

Regards,

Sheree Lynn Rybak, Ph.D.

1. – 46. (Canceled)

47. (Currently Amended) An isolated polypeptide comprising alanine 2,3-aminomutase activity.

48. (Original) The polypeptide of claim 47, wherein the polypeptide comprises a mutated lysine 2,3-aminomutase amino acid sequence.

49. (Original) The polypeptide of claim 48, wherein the mutated lysine 2,3-aminomutase amino acid sequence is a mutated *Bacillus subtilis*, *Deinococcus radiodurans*, *Clostridium subterminale*, *Porphyromonas gingivalis* or *Escherichia coli* lysine 2,3-aminomutase.

50. (Original) The polypeptide of claim 49, wherein the mutated lysine 2,3-aminomutase amino acid sequence is a mutated *Bacillus subtilis or* mutated *Porphyromonas gingivalis* lysine 2,3-aminomutase.

51. (Currently Amended) The polypeptide of claim 47, wherein the polypeptide comprises ~~amino acids 50-390 of a sequence shown in SEQ ID NO: 21 or~~ amino acids 15-390 of a sequence shown in SEQ ID NO: 30.

52. (Currently Amended) The polypeptide of claim 47, wherein the polypeptide comprises a sequence having at least 90% sequence identity to SEQ ID NO: ~~21 or~~ 30.

53. (Currently Amended) The polypeptide of claim 52, wherein the polypeptide comprises a sequence having at least 95% sequence identity to SEQ ID NO: ~~21 or~~ 30.

54. (Currently Amended) The polypeptide of claim 52, wherein the polypeptide comprises SEQ ID NO: ~~21 or~~ 30.

55. (Original) The polypeptide of claim 52, wherein the polypeptide comprises one or more conservative amino acid substitutions.

56. (Original) The polypeptide of claim 52, wherein the polypeptide comprises no more than 10 conservative amino acid substitutions.

57. (Original) An isolated nucleic acid comprising a nucleic acid sequence that encodes the polypeptide of claim 47.

58. (Original) The isolated nucleic acid of claim 57 operably linked to a promoter sequence.

59. (Currently Amended) The isolated nucleic acid of claim 57, wherein the nucleic acid comprises ~~nucleotides 307-1017 of SEQ ID NO: 20 or~~ nucleotides 55-1026 of SEQ ID NO: 29.

60. (Currently Amended) The isolated nucleic acid of claim 57,wherein the nucleic acid comprises a sequence having at least 90% identity to ~~SEQ ID NO: 20 or~~ SEQ ID NO: 29.

61. (Currently Amended) The isolated nucleic acid of claim 57,wherein the nucleic acid comprises a sequence having at least 95% identity to ~~SEQ ID NO: 20 or~~ SEQ ID NO: 29.

62. (Original) The isolated nucleic acid of claim 60, wherein the nucleic acid sequence includes one or more substitutions which results in one or more conservative amino acid substitutions.

63. (Original) The isolated nucleic acid of claim 60, wherein the nucleic acid sequence includes one or more substitutions which results in no more than 10 conservative amino acid substitutions.

64. (Currently Amended) The isolated nucleic acid of claim 61, wherein the nucleic acid comprises SEQ ID NO: ~~20 or~~ 29.

65. (Original) A vector comprising the isolated nucleic acid of claim 57.

66. (Original) A recombinant nucleic acid comprising the isolated nucleic acid of claim 57.

67. (Original) A cell transformed with the recombinant nucleic acid of claim 66.

68. (Canceled)

69. (Original) A transformed cell comprising at least one exogenous nucleic acid molecule, wherein the at least one exogenous nucleic acid molecule comprises a nucleic acid sequence that encodes the polypeptide of claim 47.

70. (Original) The transformed cell of claim 69, wherein the cell produces beta-alanine from alpha-alanine.

71. (Original) The cell of claim 70, wherein the cell produces 3-HP.

72. (Original) The cell of claim 71, wherein the cell produces 1,3-propanediol.

73. (Original) The cell of claim 70, wherein the cell produces pantothenate.

74. (Original) The cell of claim 73, wherein the cell produces CoA.

75. (Canceled)

76. (Original) A method of producing a polypeptide comprising alanine 2,3-aminomutase activity, comprising culturing the cell of claim 67 under conditions that allow the cell to produce the polypeptide comprising alanine 2,3-aminomutase activity.

77. – 106. (Canceled)

107. (Previously Presented) A transgenic plant comprising the recombinant nucleic acid of claim 57.

Claim objections

Claims 51-56 and 59-64 are objected to on the ground that they recite non-elected sequences (e.g. SEQ ID NO: 20 and 21). Applicants request reconsideration.

Claims 51-54 are amended to remove reference to SEQ ID NO: 21. Claims 59-62 and 64 are amended to remove reference to SEQ ID NO: 20. Claims 55-56 and 63 do not recite a sequence identifier and so these claims are improperly objected to.

In view of these amendments, Applicants request that the objections to the claims be withdrawn.

35 U.S.C. § 112, first paragraph (written description)

Claims 47-50, 57, 58, 65-67, 69-74, 76 and 107 are rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Applicants disagree and request reconsideration.

[EXAMINER: It appears you are requiring sequence identifiers. However, even claims with sequence identifiers are rejected. It is Applicants' position that they were the first to identify an enzyme having alanine 2,3 aminomutase activity in vivo. In such a case, are Applicants entitled to broader protection? Is there any other way of claiming a protein without providing a sequence identifier?]

35 U.S.C. § 112, first paragraph (enablement)

Claims 47-50, 52-58, 60-63, 65-67, 69-74, 76 and 107 are rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. Applicants disagree and request reconsideration.

[EXAMINER: It appears you are wanting to limit the claims to SEQ ID NO: 30. Is it not USPTO policy that it is not undue experimentation to make/screen variants with at least 95% sequence identity (e.g. claim 53)? In any event, the specification provides exemplary substitutions and functional fragments (for example on page 28, lines 17-22). In addition, the ability of a variant of SEQ ID NO: 30 to retain alanine 2,3-aminomutase activity can be directly and verified by procedures specified in the description; see for example page 8, lines 29 to 37,

and more specifically in Examples 6, page 46, line 4 to page 50, line 26, and Examples 9 to 11, page 52, lines 5 to page 63, line 35.

What if Applicants can provide evidence that numerous variants of SEQ ID NOS: 21 and 30 have been since identified and have alanine 2,3-aminomutase activity? Would evidence of such variants with functional activity overcome the 112 issues? Also, what about the sequence identity between the two disclosed sequences in SEQ ID NO: 21 and 30?]

[EXAMINER: Can you please clarify the rejection of claims 71-74?]

35 U.S.C. § 101

Claim 47 is rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter. Applicants request reconsideration.

As suggested by the examiner, claim 47 is amended to recite that the peptide is an "isolated" peptide.

In view of this amendment, Applicants request that the 35 U.S.C. § 101 rejection be withdrawn.

35 U.S.C. § 102(a, e)

Claims 47-50, 52, 53, 55-58, 60-63, 65-67, 69-74, 76 and 107 are rejected under 35 U.S.C. § 102(b) as anticipated by Frey *et al.* (US 6,248,874) as evidenced by Frey *et al.* (US 2003/0113882). Applicants disagree and request reconsideration.

The present application discloses for the first time the existence of a polypeptide having alanine 2,3-aminomutase activity in vivo. Specifically, Applicants were the first to disclose that mutation of a nucleic acid molecule encoding a lysine 2,3-aminomutase, provides a nucleic acid molecule that encodes a polypeptide having alanine 2,3-aminomutase activity.

There is no disclosure in US 6,248,874 that teaches a skilled artisan that mutating the lysine 2,3-aminomutase isolated form *Clostridium subterminale* would provide an alanine 2,3-aminomutase. Moreover, there is no disclosure in US 2003/0113882 that teaches a skilled artisan that a mutated lysine 2,3-aminomutase from *Clostridium subterminale* would *inherently* function as an alanine 2,3-aminomutase. Accordingly, the combined teachings of US 6,248,874 and US 2003/0113882 does not provide any evidence to demonstrate that a mutated lysine 2,3-

aminomutase would have alanine 2,3-aminomutase activity, thus casting serious doubt of the alleged implicit disclosure of US 6,248,874.

In addition, Applicants bring the Examiner's attention to the unusual in vitro conditions which are employed in US 2003/0113882 in order to observe alanine 2,3-aminomutase activity (see paragraphs 151-153 of US 2003/0113882). It is submitted that these conditions could not be reproduced *in vivo*, and therefore such alanine 2,3-aminutase activity would not be observed in vivo. It is Applicants' position that such activity would not be observed *in vivo*.

The inability of the enzyme disclosed in the cited art to have *in vivo* alanine 2,3-aminomutase activity is confirmed by Tables 2 and 3 of the present application, found at pages 50 and 53 respectively. The data contained in Table 2, demonstrates that native lysine 2,3 aminomutase from *P. gingivalis* does not posses alanine 2,3-aminomutase activity. The data contained in Table 3, demonstrates that native lysine 2,3 aminomutase from *B. subtilis* does not posses alanine 2,3-aminomutase activity. It is submitted that the present application teaches that native lysine 2,3-aminomutases do not possess alanine 2,3-aminomutase activity and thus casts further doubt over the alleged implicit disclosure of US 6,248,874.

[EXAMINER: It is Applicants' position that the lysine 2,3 aminomutase disclosed in the cited art does not inherently have alanine 2,3-aminomutase activity, and only arguably does so under very unusual in vitro conditions. That the lysine 2,3 aminomutase disclosed in the cited art does NOT have alanine 2,3-aminomutase activity is supported by the fact that the present inventors did not observe alanine 2,3-aminomutase activity in vivo with a lysine 2,3 aminomutase from either *P. gingivalis* or *B. subtilis*. In contrast, the enzymes provided by the present disclosure naturally have alanine 2,3-aminomutase activity. Would a declaration to this effect be helpful? The Office should not ignore the data provided by the Applicants, as it refutes what the art arguably teaches. It is not likely possible to present a side-by-side comparison to the lysine 2,3 aminomutase in the cited art as it is covered by a patent, and Applicants do not have permission to use it.

Alternatively, if Applicants can swear-behind US 2003/0113882, will the rejection go away?]